

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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BRECKENRIDGE PHARMACEUTICAL, INC.,

07 Civ. 11114

Plaintiff,

OPINION

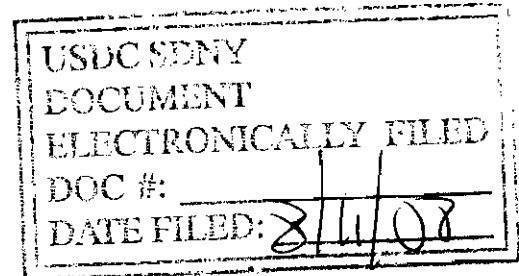
-against-

MIDLAND HEALTHCARE, LLC,

Defendant.

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A P P E A R A N C E S:



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Sweet, D.J.

In this action for breach of contract, Plaintiff Breckenridge Pharmaceutical, Inc. ("Breckenridge" or the "Plaintiff") has moved under Rule 56, Fed. R. Civ. P., for summary judgment against defendant Midland Healthcare LLC ("Midland" or the "Defendant"). The motion is granted in part and denied in part.

Prior Proceedings

Breckenridge filed its complaint on December 7, 2007, seeking \$200,000 it paid to Midland pursuant to the contract between them relating to the development of a generic drug. No discovery has been undertaken.

The instant motion was marked fully submitted on March 26, 2008.

Facts

The facts are set forth in the Breckenridge Local Civil Rule 56.1 Statement of Undisputed Facts ("Breckenridge Statement"), the Midland Rule 56.1 Declaration of Counter-

Statement of Facts in Opposition to the Motion for Summary Judgment ("Midland Counterstatement") and affidavits submitted by Larry J. Lapila, Breckenridge Vice President of Business Development ("Lapila Decl."), Robert Falconer, a consultant for Breckenridge ("Falconer Decl."), and Raman Kapur, Chairman of Midland ("Kapur Decl."). The facts are not in material dispute except as noted.

On January 26, 2007, Breckenridge and Midland entered into an ANDA Development, Manufacture, and Supply Agreement (the "Agreement"). The Agreement provided that Breckenridge was to pay Midland a certain sum for development of a prescription product (the "Product"). Breckenridge then planned to submit an Abbreviated New Drug Application ("ANDA") for approval by the United States Food and Drug Administration (the "FDA") and market the Product in the United States.

The services to be rendered by Midland pursuant to the Agreement were those required for "the development of the Product for submission of an ANDA." Agreement § 2.1(a). These "services" were further defined to include specific development steps: "formulation development, pilot-scale and scale-up batch manufacturing, analytical method development, method validation, and stability testing for the Product on site at [Midland's]

facility." Id. § 2.1(b). In Exhibit B to the Agreement, these services were broken down into certain "milestones." Exhibit B specifies payments to be made by Breckenridge to Midland upon achievement of each milestones. Id., Ex. B.

The first milestone is execution of the Agreement.

The second milestone is the "completion of formulation development," which was to be achieved 120 days after the execution of the Agreement. The Agreement defines "completion of formulation development" to include "comparative assay results for the pilot-scale batch, and successful completion of analytical method validation, including impurities." Id. § 1.7.

The third milestone, to be completed 180 days from commencement of the project, is "completion of scale-up," defined as "[t]he successful manufacture of the ANDA Exhibit Batch and receipt by Breckenridge of acceptable comparative assay results." Id. § 1.8, Ex. B.

The fourth milestone, to be completed 280 days from commencement, is "[r]eceipt by Breckenridge of satisfactory 3-month accelerated stability results for ANDA Exhibit Batch." Id., Ex. B.

Stability testing was to begin by approximately early August, 2007. Midland advised Breckenridge that stability testing had been performed on a development batch of the Product, and that appropriate progress was being made on the subsequent milestones.

Midland did not advise Breckenridge that the formulation development had not been completed.

Breckenridge paid Midland a total of \$200,000, in multiple payments. Although the Midland Counterstatement contains no reference to these payments, the Kapur affidavit asserts that Breckenridge paid Midland \$25,000 in connection with milestone 1, \$75,000 in connection with milestone 2, \$50,000 in connection with milestone 3, and \$25,000 in connection with milestone 4. Kapur Aff. ¶ 9. The dates of these payments were not set forth.

In September 2007, Lapila and Falconer conducted an on-site audit of Midland's progress and learned that Midland had not produced a pilot-scale batch, produced comparative assay results, completed analytical method validation, or performed (or even begun to perform) stability testing of the formulation.

According to Breckenridge, Midland has not rendered any of the services required by section 2.1 of the Agreement, and has achieved none of the milestones specified in Exhibit B to the Agreement except for "Execution of Agreement." According to Midland, Midland had developed a pilot formulation prior to entering the Agreement, the initial development work having been conducted in India. Midland Counterstatement ¶ 3; Kapur Decl. ¶¶ 3, 10.

On September 26, 2007, Lapila emailed Kapur that Breckenridge had learned from its site visit that stability testing had not been performed on a development batch as Midland had previously represented and that development of the Product was off schedule. Lapila subsequently emailed Kapur, on November 12, 2007: "You have put me in a VERY embarrassing position . . . This project has died due to Midland's failure to get it up on stability in a timely manor [sic] Since our visit I have found it impossible to get information from you." Lapila Decl., Ex. 3. Lapila also asked for the return of the money paid by Breckenridge to Midland. Id.

In response, Kapur twice apologized for putting Lapila in this position, requested time to complete a "restructuring

transaction," and stated that he would come back to Breckenridge "with a proposal," and was "looking into a couple of other things . . . to see what else we can do together." Id.

Section 2.3 of the Agreement states:

Midland shall submit to Breckenridge, within ten (10) days after the last day of each month that this Agreement is in effect, monthly reports describing the progress of the development of the Product, reasonably acceptable to Breckenridge. The failure of Midland to provide two (2) consecutive monthly reports in a timely manner shall be a breach giving Breckenridge a right to (i) suspend its performance under this Agreement, or, after notice by Breckenridge, (ii) terminate this Agreement in accordance with the termination provisions of this Agreement.

Midland failed to provide to Breckenridge at least two consecutive monthly reports that were required by section 2.3 of the Agreement. According to Midland, there were regular conferences concerning progress.

According to Breckenridge, Midland misrepresented the progress that had been made in the development of the Product, a statement not directly denied by Midland.

Section 7.2(b) of the Agreement provides:

Breckenridge may terminate this Agreement for Midland's breach of its material obligations hereunder; material breach is defined to include (i) failure to accomplish certain Milestones in accordance with Exhibit B, (ii) provide reports in accordance with Section 2.3 . . . at any time by giving at least sixty (60) days' prior written notice of termination to Midland, and so long as Midland fails to remedy the breach to the reasonable satisfaction of Breckenridge prior to the expiration of the sixty (60) day notice period provided the breach is capable of being cured within the 60 day period.

If Breckenridge exercises its option to terminate this Agreement in accordance with the provisions of this Section 7.2(b), Breckenridge's obligations to pay for development services shall cease upon completion of the notice period, if applicable, and Midland will prepare a reconciliatory billing for actual services rendered. The billing will represent actual time and costs reasonably incurred by Midland on the project through the date of termination. The billing will be deducted from (or added to, as the case may be) the payments made to date pursuant to Exhibit B

On November 30, 2007, Breckenridge sent to Midland a letter terminating the Agreement pursuant to section 7.2(b) of the Agreement, and the Agreement was terminated effective January 29, 2008.

Breckenridge asserts that Midland has not rendered any of the services to be provided pursuant to section 2.1 of the Agreement, and has not performed any "actual services rendered" for which it would have a right to be paid pursuant to the final

paragraph section 7.2(b) of the Agreement. This assertion is not directly denied by the Midland Counterstatement. The Midland Counterstatement does contain a recitation of certain work allegedly performed, but provides no factual basis for the assertion. See Midland Counterstatement, ¶ 4.

Midland has not returned any of the money paid to it by Breckenridge for the development of the Product.

The Summary Judgment Standard

Summary judgment is granted only if there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); see Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); SCS Commc'ns, Inc. v. Herrick Co., 360 F.3d 329, 338 (2d Cir. 2004). The courts do not try issues of fact on a motion for summary judgment, but, rather, determine "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 251-52 (1986).

"The party seeking summary judgment bears the burden of establishing that no genuine issue of material fact exists and that the undisputed facts establish [its] right to judgment as a matter of law." Rodriguez v. City of New York, 72 F.3d 1051, 1060-61 (2d Cir. 1995). In determining whether a genuine issue of material fact exists, a court must resolve all ambiguities and draw all reasonable inferences against the moving party. See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Gibbs-Alfano v. Burton, 281 F.3d 12, 18 (2d Cir. 2002). However, "the non-moving party may not rely simply on conclusory allegations or speculation to avoid summary judgment, but instead must offer evidence to show that its version of the events is not wholly fanciful." Morris v. Lindau, 196 F.3d 102, 109 (2d Cir. 1999) (quotation omitted).

Local Civil Rule 56.1(a) requires a motion for summary judgment to be accompanied by a statement, in numbered paragraphs, of material facts as to which the moving party contends there is no genuine issue to be tried. Local Civil Rule 56.1(b) requires that "[t]he papers opposing a motion for summary judgment . . . include **a correspondingly numbered paragraph responding to each numbered paragraph in the statement of the moving party**" (emphasis in original). Midland failed to respond to Breckenridge's Rule 56.1 Statement as

required by Local Civil Rule 56.1(b). As such, each properly supported fact set forth in Breckenridge's statement may be deemed admitted for the purposes of this motion. See S.D.N.Y. Civ. R. 56.1(c); see also Morriseau v. DLA Piper, 532 F. Supp. 2d 595, 618 (S.D.N.Y. 2008) ("As Judge Easterbrook has observed, '[j]udges are not like pigs, hunting for truffles buried' in the record. Where a non-moving party defaults on a properly supported motion for summary judgment, the court is not obliged to sift through a large court record against the possibility that it will find something to warrant denial of the motion that the non-moving party has not bothered to call to its attention."); Nigro v. Dwyer, 438 F. Supp. 2d 229, 231 (S.D.N.Y. 2006) (deeming the facts in movant's Rule 56.1 statement to be true where defendant filed affidavit in opposition and attorney's affirmation in opposition, but failed to file Local Rule 56.1 statement).

III. DISCUSSION

Even taking into account Midland's factual submissions, Breckenridge has established the Agreement and its terms, the payments by Breckenridge, Midland breach of the Agreement, and Breckenridge's valid termination of the Agreement.

A. Midland Breached the Agreement

To date, Midland has not rendered any of the services required by section 2.1 of the Agreement, and has completed none of the milestones specified in Exhibit B to the Agreement except milestone 1, "Execution of the Agreement."

The Midland Counterstatement asserts that "Defendant had developed a pilot formulation and Plaintiff had been informed prior to execution of the Agreement that initial development work **would be** conducted in India and be supplemented by work in the U.S.," Midland Counterstatement ¶ 2 (emphasis added) (citing Kapur Decl. ¶ 3). This is a misrepresentation of the Kapur Declaration, which states: "At the time we entered into the aforesaid Agreement . . . the initial development work **had been conducted** in India and was to be supplemented by work in the United States." Kapur Decl. ¶ 3 (emphasis added); see also id. at ¶ 10 ("In substance, Midland did complete formulation development in accordance with Milestone 2 because it was understood by Breckenridge that the stability study had been conducted in the pilot formulation that was developed in India."). Kapur's assertion that the stability study required by milestone 3 had already been completed at the time of the

Agreement is inconsistent with the terms of the Agreement, which does not contemplate compensating Midland for work it had already performed, and specifies that Midland shall perform the necessary steps to develop the Product "on site at its facility" Agreement ¶ 2.1(b). Whether or not Midland was involved in the production of a similar product in India, it did not complete that formulation development pursuant to and in furtherance of its Agreement with Breckenridge.

B. Termination of the Agreement Was Effective

Section 7.2(b) of the Agreement provides:

Breckenridge may terminate this Agreement for Midland's material breach of its obligations hereunder; material breach is defined to include (i) failure to accomplish certain Milestones in accordance with Exhibit B, (ii) provide reports in accordance with section 2.3 . . . at any time by giving at least sixty (60) days prior written notice of termination to Midland, so long as Midland fails to remedy the breach to reasonable satisfaction of Breckenridge prior to the expiration of the sixty (60) day notice period provided the breach is capable of being cured with the 60 day period.

The Agreement was terminated as of Tuesday, January 29, 2008, pursuant to Breckenridge's November 30, 2007 termination letter. Breckenridge was contractually entitled to terminate the Agreement because Midland had failed to meet the

milestones set forth in the Agreement and because Midland had failed to provide two consecutive reports as required by section 2.3.

Midland has asserted that the Breckenridge termination was ineffective because of the failure to provide a 60-day cure period.

Milestone 4 required Midland to provide Breckenridge with the results of a three-month stability study by November 2, 2007. According to Breckenridge, Midland's failure to satisfy milestone 2 on time led to its subsequent breach of its obligation to provide the milestone 4 three-month stability test results by November 2, 2007 and this breach was not "capable of being cured within the 60-day period." Midland had not produced the exhibit batch and begun the stability test as of the time Breckenridge sent the termination letter on November 30, 2007. Kapur does not aver otherwise, and in fact states that "it was understood that . . . the accelerated stability study for the ANDA, would be conducted on the exhibit batch" Kapur Decl. ¶ 10. Even if completion of the milestone on any date after the November 2 deadline could be considered a "cure," Midland could not have performed a three-month stability study in the 60 day cure period.

The termination of the Agreement was therefore in accordance with its terms.

**C. Breckenridge Has Not Established Its Right to
Recover its Payments**

It has been established that the relationship between the parties is governed by the Agreement, and that payments of \$200,000 were made by Breckenridge.

The termination provision states as follows:

If Breckenridge exercises its option to terminate this Agreement in accordance with the provisions of this Section 7.2(b), Breckenridge's obligations to pay for development services shall cease upon completion of the notice period, if applicable, and Midland will prepare a reconciliatory billing for actual services rendered. This billing will represent actual time and costs reasonably incurred by Midland on the project through the date of termination. The billing will be deducted from (or added to, as the case may be) the payments made to date pursuant to Exhibit B, and the balance owed by (or due to) either party will be paid in full within thirty (30) days after the receipt of the Midland reconciliatory billing invoice.

Breckenridge asserts that Midland did not render any of the services contracted for, and should therefore be required


to reimburse Breckenridge in full. However, the Agreement requires that "billing for actual services rendered" shall "represent actual time and costs reasonably incurred by Midland on the project through the date of termination." On this record, the Court is unable to determine what costs, if any, Midland reasonably incurred on the project through the date of termination.

Conclusion

As set forth above, the Breckenridge motion is granted in **part** and denied in part.

It is so ordered.

New York, N.Y.
August **6**, 2008



ROBERT W. SWEET
U.S.D.J.